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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/010,763 | 11/02/2001 | Isaiah J. Fidler | UTSC:684US/SLH | 2999 |

7590 02/11/2004

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| EXAMINER | |
|---|---|
| UNGAR, SUSAN NMN | |
| **ART UNIT** | **PAPER NUMBER** |
| 1642 | |

DATE MAILED: 02/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

RECEIVED
Date(s) Docketed: 3 mo Ext Response
to Keith - Reg. Due
3 mo ext final deadline
FEB 17 2004
Client: UTSC:684US
Attorney(s): DLP/SLH
Initials: SM

PTO-90C (Rev. 10/03)

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/010,763 | FIDLER ET AL | |
| | Examiner | Art Unit | |
| | Susan Ungar | 1642 | |

*– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on *02 November 2001*.

2a)☐ This action is FINAL. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☐ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) *1-33* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Claims 1-33 are pending in the application and are currently under prosecution.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

3. Claim 1 links inventions 1-5/(A)-(M)/(I)-(III)(a)-(t). The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

**Group 1.** Claims 1, 2, 3,8-14 drawn to a method for determining the effectiveness of a cancer treatment by assaying a hair follicle, classified in Class 435, subclasses 4, 7.1.

**Group 2.** Claims 1, 2, 4,8-14 drawn to a method for determining the effectiveness of a cancer treatment by assaying buccal mucosa tissue, classified in Class 435, subclasses 4, 7.1.

**Group 3.** Claims 1,2, 5,8-14 drawn to a method for determining the effectiveness of a cancer treatment by assaying a pap-smear sample, classified in Class 435, subclasses 4, 7.1.

**Group 4.** Claims 1,2,6,8-14 drawn to a method for determining the effectiveness of a cancer treatment by assaying bladder-wash cells, classified in Class 435, subclasses 4, 7.1.

**Group 5.** Claims 1,2,7-14 drawn to a method for determining the effectiveness of a cancer treatment by assaying skin scrapings, classified in Class 435, subclasses 4, 7.1.

For each of the inventions 1-5 above, restriction to one of the following is also required under 35 USC121. Therefore, election is required of one of inventions 1-5 **and** one of inventions (A)-(M). It is noted that this is not an election of species requirement in that each of the linked groups consists of one of inventions 1-5 above **and** one of inventions (A)-(M) below as claimed or disclosed in the specification.

(A) epidermal growth factor receptor

(B) fibroblast growth factor receptor

(B) acidic fibroblast growth factor receptor

(D) basic fibroblast growth factor receptor

(E) insulin like growth factor receptor

(F) nerve growth factor receptor

(G) transforming growth factor alpha receptor

(H) transforming growth factor beta receptor

(I) neuregulin receptor

(J) betacellulin receptor

(K) amphiregulin receptor

(L) heparin binding EGF-like growth factor receptor

(M) cytokine growth factor receptor

Further, for each of the inventions 1-5/(A)-(M) above, restriction to one of the following is also required under 35 USC121. Therefore, election is required of one of inventions 1-5 **and** one of inventions (A)-(M) and one of inventions (I)-(III). It is noted that this is not an election of species requirement in that each of the linked groups consists of one of inventions 1-5 above **and** one of inventions (A)-(M) **and** one of inventions (I)-(III) below as claimed or disclosed in the specification.

(I) label comprises a fluor

(II) label comprises an enzyme

(III) label comprises a radionuclide

Claims 12 and 13 will be examined as they are drawn to the elected group. Further, for each of the inventions 1-5/(A)-(M)(I-III) above, restriction to one of the following is also required under 35 USC121. Therefore, election is required of one of inventions 1-5 **and** one of inventions (A)-(M) **and** one of inventions (I)-(III) and one of inventions (a)-(x). It is noted that this is not an election of species requirement in that each of the linked groups consists of one of inventions 1-5 above **and** one of inventions (A)-(M) **and** one of inventions (I)-(III) and one of cancer inventions (a)-(t) below as claimed or disclosed in the specification.

(a) breast

(b) prostate

(c) colon

(d) pancreas

(e) head and neck

(f) bladder

(g) blood

(h) bone

(I) bone marrow

(j) brain

(k) esophagus

(l) gastrointestine

(m) kidney

(n) liver

(o) lung

(p) nasopharynx

(q) ovary

(r) skin

(s) stomach

(t) uterus

4. Claim 15 links inventions 6-19. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 15. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to

examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

**Group 6.** Claims 15-17 are drawn to a method for detecting epidermal growth factor receptor phosphorylation in hair follicles classified in Class 435, subclasses 4, 7.1.

**Group 7.** Claims 15-16 are drawn to a method for detecting fibroblast growth factor receptor phosphorylation in hair follicles classified in Class 435, subclasses 4, 7.1.

**Group 8.** Claims 15-16 are drawn to a method for detecting acidic fibroblast growth factor receptor phosphorylation in hair follicles classified in Class 435, subclasses 4, 7.1.

**Group 9.** Claims 15-16 are drawn to a method for detecting basic fibroblast growth factor receptor phosphorylation in hair follicles classified in Class 435, subclasses 4, 7.1.

**Group 10.** Claims 15-16 are drawn to a method for detecting insulin like growth factor receptor phosphorylation in hair follicles classified in Class 435, subclasses 4, 7.1.

**Group 11.** Claims 15-16 are drawn to a method for detecting nerve growth factor receptor phosphorylation in hair follicles classified in Class 435, subclasses 4, 7.1.

**Group 12.** Claims 15-16 are drawn to a method for detecting transforming growth factor alpha receptor phosphorylation in hair follicles classified in Class 435, subclasses 4, 7.1.

**Group 13.** Claims 15-16 are drawn to a method for detecting transforming growth factor beta receptor phosphorylation in hair follicles classified in Class 435, subclasses 4, 7.1.

**Group 14.** Claims 15-16 are drawn to a method for detecting neuregulin receptor phosphorylation in hair follicles classified in Class 435, subclasses 4, 7.1.

**Group 15.** Claims 15-16 are drawn to a method for detecting betacellulin receptor phosphorylation in hair follicles classified in Class 435, subclasses 4, 7.1.

**Group 16** Claims 15-16 are drawn to a method for detecting amphiregulin receptor phosphorylation in hair follicles classified in Class 435, subclasses 4, 7.1.

**Group 17** Claims 15-16 are drawn to a method for detecting heparin binding EGF-like growth factor receptor phosphorylation in hair follicles classified in Class 435, subclasses 4, 7.1.

**Group 18** Claims 15-16 are drawn to a method for detecting cytokine growth factor receptor phosphorylation in hair follicles classified in Class 435, subclasses 4, 7.1.

**Group 19** Claim 18 is drawn to a kit for determining the effectiveness of treatment with anticancer agents classified in classified in Class 530, subclass 350+.

5. Claims 19 and 25 link inventions 20-57(A)-(M)/(I)-(IV). The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 19 and 25. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

**Group 20.** Claims 19-21, 23-32 are drawn to a method of breast cancer therapy wherein said cancer treatment is designed to decrease growth factor receptor phosphorylation, classified in Class 514, subclass 2+.

**Group 21.** Claims 19-21, 23-32 are drawn to a method of prostate cancer therapy wherein said cancer treatment is designed to decrease growth factor receptor phosphorylation, classified in Class 514, subclass 2+.

**Group 22.** Claims 19-21, 23-32 are drawn to a method of colon cancer therapy wherein said cancer treatment is designed to decrease growth factor receptor phosphorylation, classified in Class 514, subclass 2+.

**Group 23.** Claims 19-21, 23-32 are drawn to a method of pancreatic cancer therapy wherein said cancer treatment is designed to decrease growth factor receptor phosphorylation, classified in Class 514, subclass 2+.

**Group 24.** Claims 19-21, 23-32 are drawn to a method of head and neck cancer therapy wherein said cancer treatment is designed to decrease growth factor receptor phosphorylation,classified in Class 514, subclass 2+.

**Group 25.** Claims 19-21, 23-32 are drawn to a method of renal cancer therapy wherein said cancer treatment is designed to decrease growth factor receptor phosphorylation,classified in Class 514, subclass 2+.

**Group 26.** Claims 19-21, 23-32 are drawn to a method of bladder cancer therapy wherein said cancer treatment is designed to decrease growth factor receptor phosphorylation,classified in Class 514, subclass 2+.

**Group 27.** Claims 19-21, 23-32 are drawn to a method of blood cancer therapy wherein said cancer treatment is designed to decrease growth factor receptor phosphorylation,classified in Class 514, subclass 2+.

**Group 28.** Claims 19-21, 23-32 are drawn to a method of bone cancer therapy wherein said cancer treatment is designed to decrease growth factor receptor phosphorylation,classified in Class 514, subclass 2+.

**Group 29.** Claims 19-21, 23-32 are drawn to a method of bone marrow cancer therapy wherein said cancer treatment is designed to decrease growth factor receptor phosphorylation,classified in Class 514, subclass 2+.

**Group 30.** Claims 19-21, 23-32 are drawn to a method of brain cancer therapy wherein said cancer treatment is designed to decrease growth factor receptor phosphorylation,classified in Class 514, subclass 2+.

**Group 31.** Claims 19-21, 23-32 are drawn to a method of kidney cancer therapy wherein said cancer treatment is designed to decrease growth factor receptor phosphorylation,classified in Class 514, subclass 2+.

**Group 32.** Claims 19-21, 23-32 are drawn to a method of liver cancer therapy wherein said cancer treatment is designed to decrease growth factor receptor phosphorylation,classified in Class 514, subclass 2+.

**Group 33.** Claims 19-21, 23-32 are drawn to a method of lung cancer therapy wherein said cancer treatment is designed to decrease growth factor receptor phosphorylation,classified in Class 514, subclass 2+.

**Group 34.** Claims 19-21, 23-32 are drawn to a method of nasopharynx cancer therapy wherein said cancer treatment is designed to decrease growth factor receptor phosphorylation,classified in Class 514, subclass 2+.

**Group 35.** Claims 19-21, 23-32 are drawn to a method of ovary cancer therapy wherein said cancer treatment is designed to decrease growth factor receptor phosphorylation,classified in Class 514, subclass 2+.

**Group 36.** Claims 19-21, 23-32 are drawn to a method of skin cancer therapy wherein said cancer treatment is designed to decrease growth factor receptor phosphorylation,classified in Class 514, subclass 2+.

**Group 37.** Claims 19-21, 23-32 are drawn to a method of stomach cancer therapy wherein said cancer treatment is designed to decrease growth factor receptor phosphorylation,classified in Class 514, subclass 2+.

**Group 38.** Claims 19-21, 23-32 are drawn to a method of uterine cancer therapy wherein said cancer treatment is designed to decrease growth factor receptor phosphorylation,classified in Class 514, subclass 2+.

**Group 39.** Claims 19-20, 22-32 are drawn to a method of breast cancer therapy wherein said cancer treatment is designed to increase growth factor receptor phosphorylation,classified in Class 514, subclass 2+.

**Group 40.** Claims 19-20, 22-32 are drawn to a method of prostate cancer therapy wherein said cancer treatment is designed to increase growth factor receptor phosphorylation,classified in Class 514, subclass 2+.

**Group 41.** Claims 19-20, 22-32 are drawn to a method of colon cancer therapy wherein said cancer treatment is designed to increase growth factor receptor phosphorylation,classified in Class 514, subclass 2+.

**Group 42.** Claims 19-20, 22-32 are drawn to a method of pancreatic cancer therapy wherein said cancer treatment is designed to increase growth factor receptor phosphorylation,classified in Class 514, subclass 2+.

**Group 43.** Claims 19-20, 22-32 are drawn to a method of head and neck cancer therapy wherein said cancer treatment is designed to increase growth factor receptor phosphorylation,classified in Class 514, subclass 2+.

**Group 44.** Claims 19-20, 22-32 are drawn to a method of renal cancer therapy wherein said cancer treatment is designed to increase growth factor receptor phosphorylation,classified in Class 514, subclass 2+.

**Group 45.** Claims 19-20, 22-32 are drawn to a method of bladder cancer therapy wherein said cancer treatment is designed to increase growth factor receptor phosphorylation,classified in Class 514, subclass 2+.

**Group 46.** Claims 19-20, 22-32 are drawn to a method of blood cancer therapy wherein said cancer treatment is designed to increase growth factor receptor phosphorylation,classified in Class 514, subclass 2+.

**Group 47.** Claims 19-20, 22-32 are drawn to a method of bone cancer therapy wherein said cancer treatment is designed to increase growth factor receptor phosphorylation,classified in Class 514, subclass 2+.

**Group 48.** Claims 19-20, 22-32 are drawn to a method of bone marrow cancer therapy wherein said cancer treatment is designed to increase growth factor receptor phosphorylation,classified in Class 514, subclass 2+.

**Group 49.** Claims 19-20, 22-32 are drawn to a method of brain cancer therapy wherein said cancer treatment is designed to increase growth factor receptor phosphorylation,classified in Class 514, subclass 2+.

**Group 50.** Claims 19-20, 22-32 are drawn to a method of kidney cancer therapy wherein said cancer treatment is designed to increase growth factor receptor phosphorylation,classified in Class 514, subclass 2+.

**Group 51.** Claims 19-20, 22-32 are drawn to a method of liver cancer therapy wherein said cancer treatment is designed to increase growth factor receptor phosphorylation,classified in Class 514, subclass 2+.

**Group 52.** Claims 19-20, 22-32 are drawn to a method of lung cancer therapy wherein said cancer treatment is designed to increase growth factor receptor phosphorylation,classified in Class 514, subclass 2+.

**Group 53.** Claims 19-20, 22-32 are drawn to a method of nasopharynx cancer therapy wherein said cancer treatment is designed to increase growth factor receptor phosphorylation,classified in Class 514, subclass 2+.

**Group 54.** Claims 19-20, 22-32 are drawn to a method of ovary cancer therapy wherein said cancer treatment is designed to increase growth factor receptor phosphorylation,classified in Class 514, subclass 2+.

**Group 55.** Claims 19-20, 22-32 are drawn to a method of skin cancer therapy wherein said cancer treatment is designed to increase growth factor receptor phosphorylation, classified in Class 514, subclass 2+.

**Group 56.** Claims 19-20, 22-32 are drawn to a method of stomach cancer therapy wherein said cancer treatment is designed to increase growth factor receptor phosphorylation,classified in Class 514, subclass 2+.

**Group 57.** Claims 19-20, 22-32 are drawn to a method of uterine cancer therapy wherein said cancer treatment is designed to increase growth factor receptor phosphorylation,classified in Class 514, subclass 2+.

For each of the inventions 20-57 above, restriction to one of the following is also required under 35 USC121. Therefore, election is required of one of inventions 20-57 **and** one of inventions (A)-(M). It is noted that this is not an election of species requirement in that each of the linked groups consists of one of inventions 20-57 above **and** one of inventions (A)-(M) below as claimed or disclosed in the specification.

(A) epidermal growth factor receptor

(B) fibroblast growth factor receptor

(B) acidic fibroblast growth factor receptor

(D) basic fibroblast growth factor receptor

(E) insulin like growth factor receptor

(F) nerve growth factor receptor

(G) transforming growth factor alpha receptor

(H) transforming growth factor beta receptor

(I) neuregulin receptor

(J) betacellulin receptor

(K) amphiregulin receptor

(L) heparin binding EGF-like growth factor receptor

(M) cytokine growth factor receptor

Further, for each of the inventions 20-57/(A)-(M) above, restriction to one of the following is also required under 35 USC121. Therefore, election is required of one of inventions 20-57 **and** one of inventions (A)-(M) and one of inventions **(I)-(III)**. It is noted that this is not an election of species requirement in that each of the linked groups consists of one of inventions 1-5 above **and** one of inventions (A)-(M) **and** one of inventions (I)-(IV) below as claimed or disclosed in the specification.

(I) protein kinase inhibitor

(II) tyrosine kinase inhibitor PK1166

(III) tyrosine kinase inhibitor C225 antibody

(IV) serine threonine kinase inhibitor

It is further noted that Applicant must elect one of Groups 1-5/(A)-(M)/(I)-(III)(a)-(t) disclosed above for the examination of claim 19(a).

**Group 58.** Claim 33 drawn to a method of screening candidate drugs that modulate growth factor receptor phosphorylation, classified in Class 435, subclass 4.

6. The inventions are distinct, each from the other because of the following reasons:

Inventions 1-5/(A)-(M)/(I)-(III)(a)-(t), 6-18, 20-57(A)-(M)/(I)-(IV), 58, are materially distinct methods which differ at least in objectives, method steps,

reagents and/or dosages and/or schedules used, response variables, and criteria for success.

The inventions of Groups 19 and 1-5/(A)-(M)/(I)-(III)(a)-(t), 6-18, 20-57(A)-(M)/(I)-(IV), 58 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the components for determining phosphorylation states of growth factor receptors in samples as claimed can be used in a materially different process such as producing an antibody against said components.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in

order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

7. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571-272-0837). The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvette Eyler, can be reached at 571-272-0871 The fax phone number for this Art Unit is (703) 305-7230.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Susan Ungar
Primary Patent Examiner
January 28, 2004